

AMENDMENTS TO THE CLAIMS

1. **(Withdrawn – Currently Amended)** A process for producing recombinant cytokine, comprising:

producing a ~~[[gene]] recombinant silkworm that incorporates~~ comprising a cytokine gene
in its ~~chromosomes~~ a chromosome of the recombinant silkworm,

producing recombinant cytokine protein in ~~the silk glands or~~ a silk gland, a cocoon
[[and]] or a silk thread of the ~~resulting gene~~ recombinant silkworm, and

recovering the recombinant cytokine protein from the silk ~~glands or cocoon and gland,~~
cocoon or silk thread of the recombinant silk worm.

2. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The process for producing recombinant cytokine according to claim 1, wherein ~~[[a]]~~ the cytokine gene encoding the recombinant cytokine protein is coupled downstream from a promoter specifically expressed in *Bombyx mori* silk glands ~~[[is]],~~ and wherein the cytokine gene and the promoter are incorporated in a chromosome.

3. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The process for producing recombinant cytokine according to claim 2, wherein the promoter specifically expressed in *Bombyx mori* silk glands is a sericin gene promoter.

4. **(Withdrawn – Currently Amended)** [[A]] The process for producing recombinant cytokine according to claim 2, wherein the promoter specifically expressed in Bombyx mori silk glands is a fibroin H chain gene promoter.

5. **(Withdrawn – Currently Amended)** [[A]] The process for producing recombinant cytokine according to any one of claims 1 through 4, wherein the cytokine gene is incorporated in Bombyx mori silkworm chromosomes using DNA originating in a transposon.

6. **(Withdrawn – Currently Amended)** [[A]] The process for producing recombinant cytokine according to claim 5, wherein the cytokine gene is located between a pair of inverted terminal sequences originating in a transposon.

7. **(Withdrawn – Currently Amended)** [[A]] The process for producing recombinant cytokine according to claim 5 [[or 6]], wherein the DNA originating in a transposon originates in an insect.

8. **(Withdrawn – Currently Amended)** [[A]] The process for producing recombinant cytokine according to claim 7, wherein the transposon originates in a piggyBac transposon originating in a lepidopteron.

9. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The process for producing recombinant cytokine according to ~~any of claims 1 through 8~~ claim 1 wherein the cytokine gene is a gene encoding interferon ~~[[gene]]~~ or a gene encoding colony stimulating factor ~~[[gene]]~~.

10. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The process for producing recombinant cytokine according to claim 9, wherein the interferon gene or the colony stimulating factor gene is feline interferon- ω gene, human interferon- β gene or feline granulocyte colony stimulating factor gene.

11. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The process for producing recombinant cytokine according to any one of claims 1 through 3, wherein cytokine is extracted from cocoon and silk thread by using contacting the cocoon and silk thread with an aqueous solvent.

12. **(Withdrawn – Currently Amended)** A ~~[[gene]]~~ recombinant *Bombyx mori* silkworm in which a cytokine gene has been inserted into a chromosome and cytokine is produced in the silkworm silk glands ~~[[or]]~~, cocoon ~~[[and]]~~ or silk thread.

13. **(Withdrawn – Currently Amended)** ~~A gene~~ The recombinant silkworm according to claim 12, wherein the cytokine gene inserted into a chromosome is an interferon gene or colony stimulating factor gene.

14. **(Withdrawn – Currently Amended)** ~~A gene~~ The recombinant silkworm according to claim 13, wherein the interferon gene or colony stimulating factor gene inserted into a chromosome is feline interferon- ω gene, human interferon- β gene or feline granulocyte colony stimulating factor gene.

15. **(Withdrawn – Currently Amended)** A vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes ~~in which~~, wherein said vector comprises a cytokine gene ~~[[is]]~~ coupled downstream from a promoter that is specifically expressed in *Bombyx mori* silk glands.

16. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to claim 15, wherein the promoter is sericin gene promoter.

17. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to claim 15, wherein the promoter is a fibroin H chain gene promoter.

18. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to any one of claims 15 through 17, wherein the cytokine gene is located between a pair of inverted terminal sequences originating in a transposon.

19. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to ~~any of claims 15 through 18~~ claim 15, wherein the cytokine gene is an interferon gene or a colony stimulating factor gene.

20. **(Withdrawn – Currently Amended)** ~~[[A]]~~ The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to claim 19, wherein the interferon gene or colony stimulating factor gene is feline interferon- ω gene, human interferon- β gene or feline granulocyte colony stimulating factor gene.

21. **(Currently Amended)** A gene cassette for expressing an exogenous protein comprising in order:

(1) an inverted repetitive sequence of a piggyBac transposon;

(2) a fibroin H chain gene promoter active expressed in *Bombyx mori* ~~expressed in silk glands, and~~ ;

~~[[(2)]]~~ (3) a gene coupled downstream from the promoter of (1), wherein the 5' terminal portion of a fibroin H chain gene of *Bombyx mori* is fused to the 5' side of an exogenous protein structural gene ~~[[,]]~~ ; and

~~[[(3)]]~~ (4) an inverted repetitive sequences sequence of a pair of piggyback transposon on both sides of the gene cassette comprising the promoter of (1) and the gene of (2) piggyBac transposon.

22. **(Currently Amended)** A gene cassette for expressing an exogenous protein comprising in order:

(1) an inverted repetitive sequence of a piggyBac transposon;

(2) a fibroin H chain gene promoter ~~active expressed~~ in *Bombyx mori* ~~expressed in~~ silk glands, ~~[[and]]~~

[[(2a)]] (3) a gene coupled downstream from the promoter ~~of (1)~~, wherein ~~[[the]]~~ a 3' terminal portion of a fibroin H chain gene of *Bombyx mori* is fused to the 3' side of an exogenous protein structural gene not containing a stop codon, or

[[(2b)]] ~~a gene coupled downstream from (1) in which~~ wherein an exogenous protein structural gene is fused to the 3' side of the 3' terminal portion of the fibroin H chain gene of *Bombyx mori*; and

(4) an inverted repetitive sequence of a piggyBac transposon.

23. **(Currently Amended)** A gene cassette for expressing an exogenous protein comprising in order:

(1) an inverted repetitive sequence of a piggyBac transposon;

(2) a fibroin H chain gene promoter ~~active expressed~~ in *Bombyx mori* ~~expressed in~~ silk glands, ~~and (2)~~ ;

(3) a gene coupled downstream from the promoter ~~of (1)~~, wherein ~~[[the]]~~ a 5' terminal portion of a fibroin H chain gene of *Bombyx mori* is fused to the 5' side of an exogenous protein structural gene not containing a stop codon, and ~~in which the~~ a 3' terminal portion of the fibroin H chain gene is fused to the 3' side of ~~[[the]]~~ an exogenous protein structural gene; and

(4) an inverted repetitive sequence of a piggyBac transposon.

24. **(Currently Amended)** The gene cassette according to claim 21 or claim 23, wherein the 5' terminal portion of the fibroin H chain gene contains a first exon, first intron and a portion of a second exon of the fibroin H chain gene.

25. **(Cancelled)**

26. **(Currently Amended)** The gene cassette according to claim ~~[[25]]~~ 24, wherein the promoter and the 5' terminal portion together comprise the DNA as shown in ~~SEQ. ID No.~~ SEQ ID NO: 22 or ~~SEQ. ID No.~~ SEQ ID NO: 23.

27. **(Previously Presented)** The gene cassette according to claim 22 or 23, wherein the 3' terminal portion of the fibroin H chain gene contains at least one codon that encodes cysteine.

28. **(Currently Amended)** The gene cassette according to claim 27, wherein the 3' terminal portion of the fibroin H chain gene ~~[[is]]~~ consists of the DNA shown in ~~SEQ. ID No.~~ SEQ ID NO: 24.

29. **(Cancelled)**

30. **(Currently Amended)** The gene cassette according to any one of claims 21 through 23, wherein ~~at least one poly A addition region selected from a poly A addition region of fibroin H chain gene, a poly A addition region of fibroin L chain gene and a poly A addition region of sericin gene~~ is present downstream from the gene cassette.

31. **(Currently Amended)** A gene cassette for inserting a gene into chromosomes of insect cells comprising inverted repetitive sequences of a pair of piggyBac transposons present on both sides of the gene cassette ~~claim 22 and~~ any one of claims 21 to 23.

32. **(Currently Amended)** An expression vector for insect cells that contains the gene cassette according to any one of claims 21 through 23.

33. **(Previously Presented)** A gene insertion vector for insect cells that contains the gene cassette of claim 31 for inserting a gene into chromosomes of insect cells.

34. **(Currently Amended)** A process for producing an exogenous protein comprising inserting the vector for insect cells according to claim 32 ~~[[or 33]]~~ into insect cells.

35. **(Previously Presented)** The process for producing an exogenous protein according to claim 34, wherein the insect cells originate in a lepidopteron.

36. **(Currently Amended)** The process for producing the exogenous protein according to claim 35, wherein the insect cells originate in ~~silkworm moths~~ (*Bombyx mori*).

37. **(Currently Amended)** The process for producing an exogenous protein according to claim 36, wherein the insect cells are silk gland cells of ~~silkworm moths~~ (*Bombyx mori*) *Bombyx mori*.

38. **(Currently Amended)** A process for producing an exogenous protein comprising producing a recombinant silkworm in which the gene cassette according to any one of claims 21 through 23 is inserted into a chromosome using a gene insertion vector for insect cells and the DNA transfer activity of piggyBac transposase, producing exogenous protein in the silk glands or cocoon and silk thread of the resulting recombinant silkworm, recovering the exogenous protein from the silk glands or silk and cocoon thread in an aqueous solution.

39. **(Previously Presented)** The process for producing an exogenous protein according to claim 38, wherein the recombinant silkworm, in which the gene cassette for expressing an exogenous protein has been inserted into a chromosome, is produced by simultaneously micro-injecting the gene insertion vector for insect cells and DNA or RNA that produces the piggyBac transposase into silkworm eggs.

40. **(Withdrawn)** A recombinant silkworm in which a gene cassette for expressing an exogenous protein according to any of claims 21 through 31 has been inserted into a

chromosome, and which has the ability to produce the exogenous protein in silk glands or silk thread.

41. **(Withdrawn)** Silk thread containing an exogenous protein produced by a recombinant silkworm according to claim 40.

42. **(New)** A process for producing an exogenous protein comprising inserting the vector for insect cells according to claim 33 into insect cells.

43. **(New)** The process for producing an exogenous protein according to claim 42, wherein the insect cells originate in a lepidopteron.

44. **(New)** The process for producing the exogenous protein according to claim 43, wherein the insect cells originate in *Bombyx mori*.

45. **(New)** The process for producing an exogenous protein according to claim 44, wherein the insect cells are silk gland cells of *Bombyx mori*.